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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,834	09/08/2003	Rene Gantier	37851-922	7681

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EXAMINER	
NEGIN, RUSSELL SCOTT	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,834	GANTIER ET AL.	
	Examiner	Art Unit	
	Russell S. Negin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-331* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-331* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 40-48, 139-144, 306-331, drawn to a modified cytokine, classified in class 435, subclass 183.

II. Claim 25, drawn to a collection of cytokines, classified in class 435, subclass 183.

III. Claims 26-28, 31-38, drawn to a nucleic acid encoding a cytokine of a method of expressing a cytokine, classified in class 536, subclass 23.1.

IV. Claims 29-30, drawn to a collection of nucleic acids, classified in class 536, subclass 23.1.

V. Claim 39, drawn to a modified cytokine with two or more mutations, classified in class 435, subclass 183.

VI. Claims 49-50, 145-147, drawn to a modified cytokine corresponding to SEQ ID NO: 183, classified in class 435, subclass 183.

VII. Claims 51-52, 148-150, drawn to a modified cytokine corresponding to SEQ ID NO: 185, classified in class 435, subclass 183.

VIII. Claims 53-54, 151-153, drawn to a modified cytokine corresponding to SEQ ID NO: 186, classified in class 435, subclass 183.

IX. Claims 55-56, 154-156, drawn to a modified cytokine corresponding to SEQ ID NO: 187, classified in class 435, subclass 183.

X. Claims 57-58, 157-159, drawn to a modified cytokine corresponding to SEQ ID NO: 188, classified in class 435, subclass 183.

XI. Claims 59-60, 160-162, drawn to a modified cytokine corresponding to SEQ ID NO: 189, classified in class 435, subclass 183.

XII. Claims 61-62, 163-165, drawn to a modified cytokine corresponding to SEQ ID NO: 190, classified in class 435, subclass 183.

XIII. Claims 63-64, 166-168, drawn to a modified cytokine corresponding to SEQ ID NO: 191, classified in class 435, subclass 183.

XIV. Claims 65-66, 169-171, drawn to a modified cytokine corresponding to SEQ ID NO: 192, classified in class 435, subclass 183.

XV. Claims 67-68, 172-174, drawn to a modified cytokine corresponding to SEQ ID NO: 193, classified in class 435, subclass 183.

XVI. Claims 69-70, 175-177, drawn to a modified cytokine corresponding to SEQ ID NO: 194, classified in class 435, subclass 183.

XVII. Claims 71-72, 178-180, drawn to a modified cytokine corresponding to SEQ ID NO: 195, classified in class 435, subclass 183.

XVIII. Claims 73-74, 181-183, drawn to a modified consensus cytokine corresponding to SEQ ID NO: 232, classified in class 435, subclass 183.

XIX. Claims 75-77, 184-186, drawn to a modified cytokine corresponding to SEQ ID NO: 196, classified in class 435, subclass 183.

XX. Claims 78-79, 187-189, drawn to a modified cytokine corresponding to SEQ ID NO: 197, classified in class 435, subclass 183.

XXI. Claims 80-81, 190-192, drawn to a modified cytokine corresponding to SEQ ID NO: 198, classified in class 435, subclass 183.

XXII. Claims 82-84, 193-195, drawn to a modified cytokine corresponding to SEQ ID NO: 199, classified in class 435, subclass 183.

XXIII. Claims 85-87, 196-198, drawn to a modified cytokine corresponding to SEQ ID NO: 200, classified in class 435, subclass 183.

XXIV. Claims 88-90, 199-201, drawn to a modified cytokine corresponding to SEQ ID NO: 201, classified in class 435, subclass 183.

XXV. Claims 91-93, 202-204, drawn to a modified cytokine corresponding to SEQ ID NO: 202, classified in class 435, subclass 183.

XXVI. Claims 94-96, 205-207, drawn to a modified cytokine corresponding to SEQ ID NO: 203, classified in class 435, subclass 183.

XXVII. Claims 97-99, 208-210, drawn to a modified cytokine corresponding to SEQ ID NO: 204, classified in class 435, subclass 183.

XXVIII. Claims 100-102, 211-213, drawn to a modified cytokine corresponding to SEQ ID NO: 205, classified in class 435, subclass 183.

XXIX. Claims 103-105, 214-216, drawn to a modified cytokine corresponding to SEQ ID NO: 206, classified in class 435, subclass 183.

XXX. Claims 106-108, 217-219, drawn to a modified cytokine corresponding to SEQ ID NO: 207, classified in class 435, subclass 183.

XXXI. Claims 109-111, 220-222, drawn to a modified cytokine corresponding to SEQ ID NO: 208 classified in class 435, subclass 183.

XXXII. Claims 112-114, 223-225,drawn to a modified cytokine corresponding to SEQ ID NO: 209 classified in class 435, subclass 183.

XXXIII. Claims 115-117, 226-228, drawn to a modified cytokine corresponding to SEQ ID,NO: 210, classified in class 435, subclass 183.

XXXIV. Claims 118-120, 229-231, drawn to a modified cytokine corresponding to SEQ ID NO: 211 classified in class 435, subclass 183.

XXXV. Claims 121-123, 232-234, drawn to a modified cytokine corresponding to SEQ ID NO: 212 classified in class 435, subclass 183.

XXXVI. Claims 124-126, 235-237, drawn to a modified cytokine corresponding to SEQ ID NO: 213, classified in class 435, subclass 183.

XXXVII. Claims 127-129, 238-240 drawn to a modified cytokine corresponding to SEQ ID NO: 214, classified in class 435, subclass 183.

XXXVIII. Claims 130-132, 241-243 drawn to a modified cytokine corresponding to SEQ ID NO: 215, classified in class 435, subclass 183.

XXXIX. Claims 133-135, 244-246 drawn to a modified cytokine corresponding to SEQ ID NO: 216, classified in class 435, subclass 183.

XL. Claims 136-138, 247-249 drawn to a modified cytokine corresponding to SEQ ID NO: 217, classified in class 435, subclass 183.

XLI. Claims 250-280, drawn to a computational method of generating a protein or peptide molecule, classified in class 702, subclass 19.

XLII. Claims 281-305, drawn to a computational method of generating a protein or cytokine having a pre-selected altered phenotype, classified in class 702, subclass 19.

Sequence Election Requirement Applicable to Groups I-V

In addition, Groups I thorugh V read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Inventions [I,II, V-XL] are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions claim different chemical compositions. There are differences in the SEQ ID NOs for each of the aforementioned groups. Each SEQ ID NO refers to a different chemical composition.

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions the different inventions serve different functions. A combination of cytokines has different properties, stabilities and activities than a single specie of cytokine.

Inventions III and IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions the different inventions serve different functions. A combination of nucleic acids has different properties, stabilities and activities than a single specie of nucleic acid.

Group [III,IV] is separate and distinct from Group [I,II,V-XL] because the inventions are directed to different chemical types regarding the critical limitations therein. For Group [I,II,V-XL], the critical feature is a polypeptide whereas for Group [III,IV] the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group [I,II,V-XL] to be directed as to its synthesis by a polynucleotide of Group [III,IV], however, the completely separate chemical types of the inventions of Groups [III,IV] and [I,II,V-XL] supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions [XLI, XLII] and [I-XL] are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions serve different functions. While inventions XLI and XLII are devoted to computer generation of a protein, Inventions I-XL are actual cytokine and nucleic acid product or processes of making cytokines. The two groups of inventions serve different scopes and thus, are distinct.

Inventions XLI and XLII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention XLII is a variant of Invention XLI that involves generating cytokines with pre-selected altered phenotypes. This aspect to the invention gives Invention XLIII a materially different design , mode of function or effect.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Specie Election for Invention I-XL

If any of Inventions I through XL is chosen, the following species election is required: The applicant must choose a single mutant (i.e. chemical substitution) from the list provided. All of the claims within the group are generic to that group serve as

generic claims. This species election is justified because each mutant is a unique and different chemical composition derived from a single molecule.

Specie Election for Group XLI-XLII

If either Invention XLI or XLII is chosen, the following specie election is required. In claims 265-267 and claims 303-305, a single value or percentage must be chosen. Each type of activity implies a different activity of a cytokine. Applicant needs to choose a single value or percentage.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ardin Marschel, Ph.D., Supervisory Patent Examiner, can be reached at (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-RSN 2/3/06

RSN 2/3/06

3 February 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER